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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,330	08/22/2001	Carl Johan Friddle	LEX-0221-USA	9990

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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,330	FRIDDLE ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's Amendment C filed August 8, 2003, was entered, canceling claim 6 and amending claim 7 to overcome the rejection of record under 35 U.S.C. §112, second paragraph. Claim 6 was previously cancelled, thus claims 2-5 and 7-11 remain herein. Applicant's several arguments filed August 8, 2003, traversing the rejection of record of claims 2-5 and 7-11 under 35 U.S.C. §101 are each addressed below. New grounds of rejection are stated hereinbelow, thus this communication is not made final.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-5 and 7-11 are for reasons of record rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

Applicant's arguments traversing the rejection of record filed August 8, 2003, have been fully considered but are not persuasive. As noted in the rejection of record, a claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed. It was previously agreed that polypeptides having amino acid sequences of SEQ IDs NOs:20 and 22 share a significant degree of amino acid sequence homology with other, prior art, human metalloproteases, yet claims 2-5 and 7 lack utility because the specification has no disclosure of a specific *in vitro* utility for the isolated nucleic acid sequences of either of SEQ IDs NOs:19 and 21, nor has it any disclose of a specific *in vitro* utility for an isolated nucleic acid having a generic nucleotide sequence encoding either of the amino acid sequences of SEQ IDs NOs:20 or 22. The specification has no disclosure of a specific *in vivo* utility for a nucleic acid encoding either of the amino acid

sequences of SEQ IDs NOs:20 or 22 nor has it any disclosure of a specific *in vivo* utility for the encoded products. A single disclosure within the specification's 29 pages relates to Applicant's arguments, the sentence at page 2, lines 2-5: "The novel human proteins (NHPs) described . . . herein share structural similarity with animal proteases and particularly zinc metalloproteases." This minimal disclosure cannot sustain Applicant's arguments that a product encoded by polynucleotide sequences of SEQ IDs NOs: 19 and 21 is a member of a specific metalloprotease family such as the ADAMTS family, fails to indicate that an encoded product can cleave any specific substrate, whether intracellular or extracellular, and does not suggest that the claimed polynucleotides are comprised of exon regions present on any specific chromosome.

Applicant points to Example 10 of the Revised Interim Utility Guidelines Training Materials of the USPTO to support a conclusion that a subsequent discovery by others that a particular ADAMTS family member, ADAMTS-14, exhibits a specific activity with a specific substrate retroactively constitutes a disclosure of a specific utility for a claimed polynucleotide encoding a particular protease sharing a great degree of identity with the ADAMTS-14 product. The Example that Applicant promotes concerns a polynucleotide encoding a member of a specific family of enzymes, DNA ligases, wherein all members have a common, "well-established" utility, DNA ligation. In the Example the substrate is fungible, because a DNA ligase acts on any DNA sequence. By contrast, there is no common "well-established" utility established in the art for proteases generally, nor for metalloproteases generally, nor for zinc metalloproteases generally, nor even a general utility for ADAMTS family members. Instead, experimentation is required to determine whether an ADAMTS family member is an endoprotease or an exoprotease and further experimentation is needed to find a substrate that a particular ADAMTS family member can recognize and cleave. Thus the circumstances Example 10 concerning a situation where a specification need not assert a "well-established" utility that is already "readily

apparent" to one of ordinary skill in the art are inappropriate to the absence of particular, or specific, disclosures of a utility for an invention claimed herein which has no "well-established" utility already "readily apparent" to one of ordinary skill in the art.

Pages 5-7 of the specification discuss the use of claimed polynucleotide sequences in addressable arrays of "gene chips" to identify and characterize temporal and tissue-specific expression of non-specific genes. It is agreed that the utility of a method of use of this technology is substantial but Applicant can only retroactively argue that a claimed polynucleotide might have a specific use based on the subsequent discovery of others of a function for a product encoded by a very homologous transcript. Applicant also argues that a failure to issue a patent bearing the presently-rejected product claims would disregard a Constitutional right to due process, citing six U.S. patents that describe methods of using, and apparatus for using addressable oligonucleotide arrays. Yet none of the six U.S. Patents Applicant cites discusses any requirement for, or even mentions, polynucleotides of oligonucleotides encoding all or a portion of a metalloprotease or representing a metalloprotease exon region. There is no doubt that the instant specification enables the subject matter of claims rejected herein but nothing in the record establishes that Applicant discloses a specific utility for either a native polypeptide encoded by a claimed nucleic acid sequence known to the inventors, at the time the application was filed permitting an immediate use by the public of a disclosed nucleic acid sequence, or any use by the public of an expression vector or cell comprising a disclosed nucleic acid sequence. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The rejection of record is therefore sustained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to exemplify or describe the preparation of divergent nucleic acid sequences of claims 2 and 3 where the term "stringent" is a relative term and the specification describes, at pages 4-5 two separate kinds of stringency. Thus claims 2 and 3 reach generic nucleic acid sequences that encode proteins differing significantly from those having the amino acid sequences set forth in SEQ IDs NOs:20 and 22, but neither the claims nor the specification describe where the amino acid sequence differences may occur nor what the differences might be. The specification does not otherwise disclose or suggest the nature or source of any of the myriad generic nucleic acid sequences that meet the limitations of the claims. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). In addressing the issue of whether a disclosure of a molecular structure of an informational molecule of one biological species could adequately describe the molecular structure of a functionally similar molecule of another biological species, the Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention".

University of California v. Eli Lilly, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Like the claims invalidated by the appellate panel in *University of California v. Eli Lilly*, claims 2 and 3 are designed to embrace nucleic acid sequences encoding other, as yet unknown, human proteins. Nothing demonstrates that Applicant was "able to envision" enough of the structure of any of these undisclosed generic proteins to provide the public with identifying "characteristics [that] sufficiently distinguish it . . . from other materials", at the time the specification was filed. *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the coding capacities or other properties of generic nucleic acid sequences of claims 2 and 3.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specification describes, at pages 4-5, two kinds of "stringent conditions" but neither of these different conditions are required by clause (b) of claim 2 which, indeed, permits any hybridization conditions more "stringent" than other hybridization conditions where the term "stringent" is a relative term absent any reference conditions stated in the claim. Claim 3 is included in this rejection of claim 3 because it depends therefrom thus incorporates the indefinite description of the independent claim without otherwise resolving its ambiguity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
February 12, 2004

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER